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Remarks

Claims 1-24 were previously pending in the subject application. By this Amendment, claims 1, 6, 9, 14, 17, and 22 have been amended. No new matter has been added by these amendments. Support for the amendments to claims 1, 9 and 17 can be found at, for example, page 10, lines 24-25 and page 1, lines 5-6 of the specification. Claims 6, 14, and 22 have been amended to correct typographical errors. Accordingly, claims 1-24 remain before the Examiner for consideration.

The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. The amendments should not be taken to indicate the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

As an initial matter, the applicants respectfully request that the examiner send the applicants an initialed copy of the PTO Form SB/08, which was submitted with the applicants' Information Disclosure Statement filed November 7, 2005.

The applicants wish to thank the Examiner for the careful review of the claims. As noted above, claims 6, 14 and 22 and the specification have been amended herein to correct the biological name of the organism *Bacillus licheniformis* as suggested by the Examiner.

Claims 1-3, 6-11, 14-19 and 22-24 have been rejected under 35 U.S.C. §103(a) as being obvious over Grey *et al.* (U.S. Patent No. 5,714,472) in view of McCabe (U.S. Patent No. 6,830,766) and Davis *et al.* (U.S. Patent No. 6,998,259) as evidenced by Fritsche *et al.* (U.S. Patent No. 6,737,076). Also, claims 4, 5, 12, 13, 20 and 21 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Grey *et al.* (U.S. Patent No. 5,714,472) in view of McCabe (U.S. Patent No. 6,830,766) and Siegenthaler (*The Potential Value of Cultured Dairy Products for Child Nutrition*, abstract). The applicants respectfully traverse these grounds of rejection because the references, either taken alone or in combination, do not teach or suggest the claimed nutritional compositions or their use.

Initially, please note that, at column 2, lines 56-60 and column 8 lines 58-66, Gray *et al.* state that the use of whole proteins in an enteral nutritional formulation for intensive care patients is

undesirable. Specifically, Gray *et al.* disclose that "an advantage of the present invention is that nutrient malabsorption is reduced by the absence of whole proteins (column 2, lines 56-60)" and that "[m]any of the patients receiving the whole protein diet were unable to receive the recommended calorie and protein intakes...because of intolerance and diarrhea" (column 8 lines 58-66). Therefore, even if McCabe discloses a protein derived from fermented milk such as protein from yogurt, and Siegenthaler discloses the nutritive value of cultured dairy products such as Quark, a skilled artisan would not have been motivated to use such whole proteins as a protein source for the enteral formulation of Gray *et al.*

The applicants would also like to bring the Examiner's attention to column 2, lines 51-55 of Gray *et al.*, which discloses that the content of water and carbohydrate has been reduced in order to reduce the risk of diarrhea due to carbohydrate intolerance, hyperglycemia, and over hydration. Gray *et al.* further teach at column 5, lines 53-64, that the incidence of diarrhea should be reduced. On the other hand, it is well known in the art that excessive intake of polyols (sugar alcohols) can cause diarrhea. Thus, although McCabe discloses the use of slowly metabolizable carbohydrate source (i.e., polyols), a skilled artisan would not have considered it to be suitable as a carbohydrate source of the enteral formulation of Gray *et al.*

Accordingly, the applicants respectfully submit that the combinations of references as set forth in the current Office Action do not establish a *prima facie* case of obviousness. However, in order to expedite prosecution, the applicants have amended claims 1, 9 and 17 herein to specify the protein content to be 2.9 to 9 g per 100 mL of the composition.

It is to be noted that Gray *et al.* and McCabe primarily aim at providing a composition having a high protein content (*e.g.*, Gray *et al.*, column 2, lines 46-49), or a high-protein foodstuff (*e.g.*, McCabe, abstract, line 1). More specifically, Gray *et al.* disclose at column 6, lines 13-15 that, preferably, protein comprises 25% by calories of the product, which is equivalent to 94 grams/liter (9.4 g/100 ml). McCabe discloses at column 2, line 52 to column 3, line 10, that the high protein foodstuff should have more than about 25% by weight of protein (25 g/100 g). On the other hand, the instant specification discloses at page 1, lines 30-33, that in patients with chronic liver failure, the protein catabolism is enhanced, and thus, excess protein administration may lead to

hyperammonemia. In view of this situation, traditional nutritional management of patients with enhanced protein catabolism involved reducing the protein content in the foods; however, the nutritional composition of the present invention enabled the intake of proteins at a certain amount. This protein content is low, compared to those disclosed by Gray *et al.* or McCabe.

The nutritional composition of the present invention comprises both milk protein hydrolysates and proteins derived from fermented milk as proteins, the content of which may be 0.9-3 g per 100 ml of product and 2-6 g per 100 ml of product, respectively (see page 10, lines 24-25, and page 11, lines 5-6). In other words, the protein content of the nutritional composition of the present invention may be 2.9 to 9 g per 100 ml of the composition. This protein content is not suggested by or disclosed by Gray *et al.* or McCabe. Further, it would not have been obvious for a skilled artisan to arrive at this protein content, because neither McCabe nor Gray *et al.*, which aims at providing compositions with a high protein content, disclose or suggest reducing the protein content of the composition.

It has been well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless the prior art suggested the desirability of the modification. In re Gordon, 221 USPQ 1125,1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, "[b]oth the suggestion and the expectation of success must be founded in the prior art ..." In re Dow Chemical Co. 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). An assertion of obviousness without the required suggestion or expectation of success in the prior art is tantamount to using applicant's disclosure to reconstruct the prior art to arrive at the subject invention. Hindsight reconstruction of the prior art cannot support a §103 rejection, as was specifically recognized by the CCPA in In re Sponnoble, 56CCPA 823, 160 USPQ 237, 243 (1969). In the current case, the applicants' unique formulation (and its use) are not disclosed, or even suggested, by the cited references, even when these references are taken in combination.

Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) based on Grey *et al.* in view of McCabe and Davis *et al.* as evidenced by Fritsche *et al.* The applicants further respectfully request reconsideration and

withdrawal of the rejection under 35 U.S.C. §103(a) based on Grey *et al.* (U.S. Patent No. 5,714,472) in view of McCabe (U.S. Patent No. 6,830,766) and Siegenthaler (*The Potential Value of Cultured Dairy Products for Child Nutrition*, abstract).

Claims 1-24 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 of copending Application No. 10/487,237.

The applicants would like to defer substantive response to this rejection until allowable subject matter has been established in the current application, or until the copending application has matured into a patent.

In view of the foregoing remarks and the amendment above, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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